

REMARKS

Claim 1 has been amended to recite that “a vitamin is dispersed in a matrix consisting essentially of an emulsion-forming composition” Support for this amendment is found in the specification at, for example, page 5, lines 7-11 and page 7, lines 7-24. Claim 1 has also been amended to recite that “the fat-soluble vitamin is present in the powder composition in the form of solid droplets.” Support for this amendment is found in the specification at, for example, page 2, lines 24-26 and line page 4, lines 17-26. In addition, claim 1 has been amended to incorporate the subject matter of claim 2, which has been cancelled without prejudice. Support for this amendment is found in the specification at, for example, page 4, lines 21-24 and in original claim 2. See, *In re Gardner*, 177 USPQ 396, 397 (CCPA 1973) and MPEP §§ 608.01(o) and (l).

It is submitted that no new matter has been introduced by the foregoing amendments. Approval and entry of the amendments is respectfully solicited.

Rejection under 35 USC § 112, Second Paragraph

Claims 1-51 and 17 were rejected under 35 USC §112, second paragraph. (Paper No. 8 at 2.) In making the rejection, the Examiner asserted that the “instant claims recite droplets, however a powder composition is claimed. However, the term “droplets” refers to liquids.” (*Id.*)

Claim 1 has been amended to recite “solid droplets.” Accordingly, the rejection has been rendered moot and should be withdrawn.

Rejection under 35 USC § 102

Claim 1-14 were rejected under 35 USC §102(b) as anticipated by Leuenberger, EP 0 565 989 ("Leuenberger '989"), relying upon U.S. Patent No. 5,668,183 as an English translation ("Leuenberger '183"). (Paper No. 8 at 3.)

For the reasons set forth below, the rejection, respectfully is traversed.

Leuenberger '183 discloses "stable, cold water-dispersible preparations of fat-soluble substances ... contain[ing] a water-soluble or water-dispersible *lignin derivative as the matrix component*." (Col. 1, lines 43-46.)

In making the rejection, the Examiner contended only that Leuenberger '183 "discloses gelatin or gum Arabic powder compositions for vitamins where the powder composition has a particle size within the instant range. [Leuenberger] also discloses the instant vitamins and ranges/amounts." (Paper No. 8 at 3.)

As is well settled, anticipation requires "identity of invention." *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply*, 33 USPQ2d 1496, 1498 (Fed. Cir. 1995). There must be ***no difference between what is claimed and what is disclosed in the applied reference***. *In re Kalm*, 154 USPQ 10, 12 (CCPA 1967); *Scripps v. Genentech Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991). "Moreover, it is incumbent upon the Examiner to ***identify wherein each and every facet*** of the claimed invention is disclosed in the applied reference." *Ex parte Levy*, 17 USPQ2d 1461, 1462 (BPAI 1990). The Examiner is required to point to the disclosure in the reference "***by page and line***" upon which the claim allegedly reads. *Chiong v. Roland*, 17 USPQ2d 1541, 1543 (BPAI 1990).

Initially, we note that the rejection provides no evidence that Leuenberger '183 is an accurate translation of Leuenberger '989. The Examiner has made no findings of fact to determine what, if anything, was added to or subtracted from the EP publication when it was filed in the U.S. Thus, the rejection is based on a hope or belief that Leuenberger '989 and '183 disclose the same subject matter. Because the rejection fails to meet its evidentiary burden, it should be withdrawn for this reason alone.

Leuenberger '183 discloses "preparations of fat-soluble substances ... contain[ing] a water-soluble or water-dispersible ***lignin derivative as the matrix component.***" (Col. 1, lines 43-46.) Lignins are identified, in Leuenberger '183, as "irregular polymers of methoxylated phenylpropane monomers having a molecular weight estimated to be at least 20 kD." (Col. 2, lines 11-15.) In contrast, claim 1 recites that the "vitamin is dispersed in a ***matrix consisting essentially of an emulsion-forming composition selected from the group consisting of a natural polysaccharide gum, a mixture of polysaccharide gums, a protein, a mixture of proteins, and mixtures thereof....***"

The rejection fails to identify where in Leuenberger '183 a matrix is disclosed that consists essentially of a natural polysaccharide gum, a mixture of polysaccharide gums, a protein, a mixture of proteins, or mixtures thereof. Accordingly, the rejection fails to set out a *prima facie* case under §102(b) and should be withdrawn.

Rejections under 35 USC § 103

Claims 1-15 were rejected under 35 USC §103(a) as being unpatentable over Leuenberger. (Paper No. 8 at 4.)

For the reasons set forth below the rejection, respectfully is traversed.

Leuenberger is discussed above.

In making the rejection, the Examiner asserted that Leuenberger discloses "gelatin or gum Arabic powder compositions for vitamins where the powder composition has a particle size within the instant range." (Paper No. 8 at 4.) The Examiner acknowledged, however, that Leuenberger "does not teach the moisture content of the powder...." (*Id.*)

The Examiner offered nothing to fill the acknowledged gap, but merely concluded that "it would have been obvious ... to achieve the instant moisture content based upon the motivation of insuring dryness and good flowability." (*Id.*)

As is well settled, the Examiner bears the burden to set forth a *prima facie* case of unpatentability. *In re Glaug*, 62 USPQ2d 1151, 1152 (Fed. Cir. 2002); *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); and *In re Piasecki*, 223 USPQ 785, 788 (Fed. Cir. 1984). If the PTO fails to meet its burden, then the applicant is entitled to a patent. *In re Glaug*, 62 USPQ2d at 1152.

We, again, note that the rejection provides no evidence that Leuenberger '183 is an accurate translation of Leuenberger '989. The Examiner has made no findings of fact to determine what, if anything, was added to or subtracted from the EP publication when it was filed in the U.S. Thus, the rejection is based on a hope or belief that Leuenberger '989 and '183 disclose the same subject matter. Because the

rejection fails to meet its evidentiary burden, it should be withdrawn for this reason alone.

We note also that the rejection uses the wrong standard for determining obviousness. The rejection relies upon an “***obvious to ... achieve***” standard that is not found in the statute or precedential authority. Whether or not it would be “obvious to achieve” an element identified in a claim is irrelevant. A § 103 analysis requires an Examiner to identify the motivation or suggestion to modify a cited document to arrive at the claimed invention as a whole. Because the rejection relies on an improper standard – an “obvious to achieve” standard – the rejection is deficient as a matter of law and should be withdrawn for this reason alone.

Notwithstanding the legally insufficient nature of the rejection, we demonstrate below why the rejection is also devoid of the requisite facts to support a *prima facie* case under § 103.

As is fundamental, a *prima facie* case of obviousness must be based on facts, “cold hard facts.” *In re Freed*, 165 USPQ 570, 571-72 (C.C.P.A. 1970). When the rejection is not supported by facts, it cannot stand. *Ex parte Saceman*, 27 USPQ2d 1472, 1474 (B.P.A.I. 1993). In the absence of a *prima facie* case of obviousness, an applicant who complies with the other statutory requirements is entitled to a patent. See *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

Further, “to establish *prima facie* obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art.” MPEP § 2143.03 (8th ed., August 2001) (citing *In re Royka*, 180 USPQ 580 (CCPA 1974)). The rejection,

however, identifies nothing in Leuenberger '183 which discloses or suggests a "matrix consisting essentially of an emulsion-forming composition selected from the group consisting of a natural polysaccharide gum, a mixture of polysaccharide gums, a protein, a mixture of proteins, and mixtures thereof..." as recited in claim 1. In fact, Leuenberger discloses the use of a completely different material, "lignin," as the major component of the matrix to avoid.

For this reason, the rejection is factually deficient and should be withdrawn.

Furthermore, if a proposal for modifying one or more documents renders such documents inoperable or destroys their intended purpose, then the requisite motivation to make the modification would not have existed, and any rejection based on such a proposed modification would have to fail. (See, e.g., *In re Fritch*, 23 USPQ2d 1780, 1783, n. 12 (Fed. Cir. 1992) and *In re Ratti*, 123 USPQ 349, 352 (CCPA 1959) (holding the suggested combination of references improper under § 103 because it "would require a substantial reconstruction and redesign of the elements shown in [a prior art reference] **as well as a change in the basic principles under which [that reference's] construction was designed to operate.**")

Leuenberger '183 discloses the use of a matrix in which the major component is lignin. (Col. 1, lines 43-46.) Leuenberger '183 discloses that lignin is superior to gelatin and gum arabic because they "do not always have the desired dispersibility in cold water..." (Col. 1, lines 32-34.) In fact, Leuenberger '183 actually teaches away from using gelatin and gum arabic. (Col. 1, lines 18-34.) To modify Leuenberger as proposed in the rejection would require using gelatin or gum Arabic as

a major component. But as noted above, it is impermissible to modify a document to fundamentally alter the principles under which it was designed to operate.

For this additional reason, the rejection should be withdrawn.

Claim 17 was rejected under 35 USC §103(a) as being unpatentable over Leuenberger in view of Finnan *et al.*, U.S. Patent No. 4,830,859 ("Finnan"). (Paper No. 8 at 4.)

For the reasons set forth below the rejection, respectfully is traversed.

Leuenberger is summarized above.

Finnan discloses "a process for preparing lubricated water-soluble vitamin powder ... [which] is directly compressible into tablets." (Col. 1, lines 10-15.)

In making the rejection, the Examiner relied on his previous characterization of Leuenberger '183. (Paper No. 8 at 4.) The Examiner acknowledged, however, that Leuenberger "does not teach incorporating the powder into tablets." (*Id.*)

To fill the acknowledged gap, the Examiner relied on Finnan as disclosing "formation of vitamin powder into tablets." (*Id.*)

The Examiner then summarily concluded that "it would have been obvious ... to form the powder of [Leuenberger] into tablets with the motivation of providing a convenient dosage form for administration of the vitamin." (*Id.*)

Initially, we note that the rejection provides no evidence that Leuenberger '183 is an accurate translation of Leuenberger '989. Because the rejection failed to meet its evidentiary burden, it should be withdrawn for this reason alone.

see MPEP 901, 05

Moreover, as is well settled, a rejection under § 103 must demonstrate *where* in the cited documents there was a suggestion which would have “strongly motivated” one to carry out the invention as claimed. *Ex parte Graselli*, 231 USPQ 393, 394 (Bd. App. 1986). The type of motivation which would have “*impelled*” one to do so (*Ex parte Levengood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993)), and the type of suggestion that the changes “*should*” be made. *Ex parte Markowitz*, 143 USPQ 303, 305 (Bd. App. 1964).

However, the rejection points to nothing in the cited documents which would provide the motivation to combine the cited documents as suggested. An Examiner’s belief or conjecture is no substitute for statutory prior art. *In re Kratz*, 201 USPQ 71, 76 (CCPA 1979) (citing *In re Antonie*, 195 USPQ 6 (CCPA 1977)) (“We have previously rejected the argument that undirected skill of one in the pertinent art is an adequate substitute for statutory prior art.”). However, speculation is all that the rejection offers. For this reason alone the rejection is deficient and should be withdrawn.

As previously discussed, “to establish *prima facie* obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art.” MPEP § 2143.03 (8th ed., August 2001) (citing *In re Royka*, 180 USPQ 580 (CCPA 1974)). The rejection, however, identifies nothing in Leuenberger which discloses or suggests a “matrix *consisting essentially of* an emulsion-forming composition selected from the group consisting of a natural polysaccharide gum, a mixture of polysaccharide gums, a protein, a mixture of proteins, and mixtures thereof...” In fact,

Leuenberger discloses the use of a lignin as the *major* component of the matrix to avoid the stated infirmities of gums and gelatin.

For this additional reason, the rejection is factually deficient and should be withdrawn.

Furthermore, the modification of Leuenberger as suggested by the examiner would require a fundamental change in the basic principles of Leuenberger. As noted above, in such an instance the required motivation to make the modification would not have existed, and any rejection based on such a proposed modification would have to fail. (See, e.g., *In re Fritch*, 23 USPQ2d 1780, 1783, n. 12 (Fed. Cir. 1992) and *In re Ratti*, 123 USPQ 349, 352 (CCPA 1959)).


Accordingly, the suggested modification of Leuenberger in combination with Finnan is improper. For this additional reason, the rejection should be withdrawn.

Accordingly, for the reasons set forth above, entry of the amendments, withdrawal of the rejections, and allowance of the claims is respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Box Non-Fee Amendment, Commissioner for Patents, Washington, D.C. 20231, on September 19, 2002.


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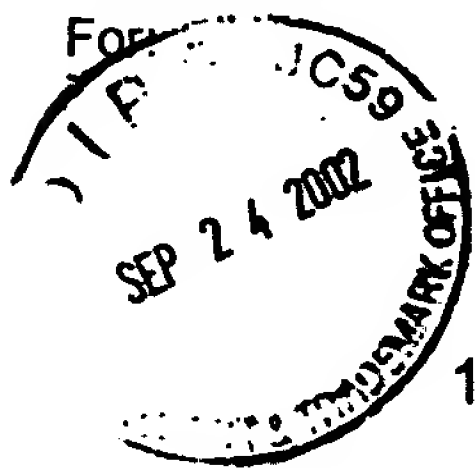
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In re Application of:
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A VITAMIN POWDER COMPOSITION AND METHOD OF MAKING



MARKED-UP VERSION OF AMENDED CLAIMS

1. (Amended) A powder composition comprising at least one fat-soluble vitamin, wherein a vitamin is dispersed in a matrix consisting essentially of [comprising] an emulsion-forming composition selected from the group consisting of a natural polysaccharide gum, a mixture of polysaccharide gums, a protein, a mixture of proteins, and mixtures thereof, wherein the fat-soluble vitamin is present in the powder composition in the form of solid droplets having an average diameter of about 70 to about 150 [200] nanometers (nm).